Citation:

Sloth B, Krog-Mikkelsen I, Flint A, Tetens I, Bjorck I, Vinoy S, Elmstahl H, Astrup A, Lang V, Raben A. No difference in body weight decrease between a low-glycemic-index and a high-glycemic-index diet but reduced LDL cholesterol after 10-wk ad libitum intake of the low-glycemic-index diet. Am J Clin Nutr 2004; 80: 337-347.

PubMed ID: 15277154

Study Design:

Randomized Controlled Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To investigate the long-term effects of a low-fat, high-carbohydrate diet with either low glycemic index or high glycemic index carbohydrates on ad libitum energy intake, body weight, and body composition, as well as on risk factors for type 2 diabetes and ischemic heart disease in overweight healthy subjects.

Inclusion Criteria:

Healthy, slightly overweight women aged 20 - 40 years, BMI 25 - 30, body weight fluctuations < 5 kg over previous 2 months, normal to mildly hypertensive blood pressure (<159/99 mm Hg), consumption of <14 alcoholic drinks/week, nonsmokers, and premenopausal with regular menstrual cycles.

Exclusion Criteria:

No physiological or psychological illnesses that could influence the study results, no regular use of medications other than birth control pills, no food allergies, no special diets or particular dislikes, no elite athletes, not planning to change physical activity during the study, not pregnant or lactating, no blood donations within the past 3 months of entering study.

Description of Study Protocol:

Recruitment

Women recruited by local newspaper advertisements and from local universities by posted announcements.

Design

Parallel randomized intervention trial with 2 matched groups.

Blinding used (if applicable)

Not used.

Intervention (if applicable)

Subjects followed low glycemic index or high glycemic index diet for 10 weeks.

Statistical Analysis

Power calculations made before the study showed that a total of 43 subjects was needed to obtain a significant ($P < 0.05$) difference in body weight change of 2.0 kg (SD = 2.0) with a power of 90%. Differences between groups in baseline values analyzed with Student's unpaired t test. Differences between groups in week 0 to week 10 in fasting blood sample values, anthropometric measurements, heart rate and blood pressure were analyzed using ANCOVA with baseline values as cofactors. The mean changes from week 0 to week 10 within the 2 groups in fasting blood sample values, anthropometric measurements, heart rate and blood pressure data were analyzed with Student's paired t test. Residual plots from weight change analysis showed clear pattern of lower residuals for high and low predicted values. Total body weight over time was analyzed by using repeated measurements to test the effect of diet, time and the diet x time interaction with baseline value as a cofactor. Data on total energy intake, energy density, macronutrient composition, and sucrose, starch and dietary fiber intakes from the dietary records were analyzed using a split-plot model testing diet, time and diet x time interaction with baseline values as cofactors. In addition, the mean energy intakes for weeks 5 and 10 were calculated, and differences between groups were tested by using ANCOVA with baseline values as cofactors. EI/BMR for the 3 dietary record periods was analyzed for differences between groups with the use of Student's unpaired t test.

Data Collection Summary:

Timing of Measurements

Before the study, subjects completed a physical activity questionnaire and Three-Factor Eating Questionnaire. On first day and last day of the study (10 weeks), measurements were taken. Body weight also measured at weeks 2, 4, 6 and 8.

Dependent Variables

- Body weight of subjects dressed in underwear measured to nearest 0.05 kg with digital scale
- Height measured to nearest 0.5 cm in subjects not wearing shoes by wall-mounted stadiometer
- Blood pressure and heart rate measured with fully automatic blood pressure monitor after resting in supine position for 15 minutes
- Sagittal height (height of abdomenafter exhalation while subject in supine position) measured to nearest 0.5 cm
- Waist and hip circumference measured to nearest 0.5 cm at narrowest point between iliac crest and lowest rib and at the broadest point below the iliac crest
- Body composition through whole body DXA while subjects dressed in light clothing and not wearing metal
- Fasting blood samples analyzed for glucose, insulin, nonesterified fatty acids, triacylglycerol, and total, LDL and HDL cholesterol

- 24-hour urine collection to determine urinary nitrogen excretion, analyzed for aromatic amines by colorimetric method using a spectrophotometer

Independent Variables

- Diet with either low-glycemic-index or high-glycemic-index carbohydrates, 55-60% calories from carbohydrates, <30% from fat. Subjects received test foods every week and were instructed to measure and record exact amounts eaten every day by using digital scale and food diary. Daily diary also asked for info on feces pattern, visual analog scales for hunger, fullness and well-being, medication, and menstruation. Subjects completed a 7-day weighed dietary record just before entering the study and in weeks 5 and 10 of the study period. Energy requirements based on FAO/UNU/WHO formulas. Subjects received individual guidance from RDs on first day of study and at group meetings in weeks 3, 5, 7 and 9. Carbohydrate quality determined using in vitro methods.

Control Variables

Description of Actual Data Sample:

Initial N: 55 suitable and willing subjects entered study.

Attrition (final N): 48 completed. 2 subjects in HGI diet group dropped out for personal reasons and study too demanding. 5 subjects in LGI diet group dropped out for study too demanding, infection, and hospitalized son. Of 48 completers, 2 HGI subjects did not fully comply with protocol and 1 LGI subject was pregnant. Data analyzed for 45 women, low glycemic index (n=23) and high glycemic index (n=22).

Age: LGI diet group: 28.9 +/- 1.3 (range 21 - 41 years), HGI diet group: 30.8 +/- 1.3 (range 20 - 40 years).

Ethnicity: Not mentioned.

Other relevant demographics: BMI LGI diet group: 27.6 +/- 0.3 (range 24.5 - 30.5), HGI diet group: 27.6 +/- 0.3 (range 25.5 - 29.9).

Anthropometrics Subjects randomly assigned to 2 groups, matched for age, body weight, height, BMI, blood pressure, heart rate, estimated energy expenditure, and alcohol intake. There were no significant differences between groups in baseline values.

Location: Copenhagen and Frederiksberg, Denmark

Summary of Results:

	LGI Baseline	LGI 5 weeks	LGI 10 weeks	HGI Baseline	HGI 5 weeks	HGI 10 weeks

Energy intake (MJ/day)	9.5 +/- 0.3	9.2 +/- 0.3	8.7 +/- 0.3	9.8 +/- 0.4	9.8 +/- 0.3	9.5 +/- 0.3

Other Findings

Subjects ate >95% of the amounts of test foods they were requested to eat, showing strong compliance.

There was a significant decrease in energy intake with time, but there were no significant differences between groups. No significant differences between groups were seen in macronutrient composition or alcohol, sucrose, starch or dietary fiber intakes.

Diaries showed no difference between groups in fecal patterns or in ratings of fullness, hunger, or well-being.

Energy intake, mean body weight change (LGI diet: -1.9 +/- 0.5 kg; HGI diet: -1.3 +/- 0.3 kg, P = 0.31), and fat mass (LGI diet: -1.0 +/- 0.4 kg, HGI diet: -0.4 +/- 0.3 kg, P = 0.20) decreased over time, but the differences between groups were not significant.

No significant differences were observed between groups in resting heart rate, blood pressure, fasting serum insulin, homeostasis model assessment for relative insulin resistance, homeostasis model assessment for beta-cell function, triacylglycerol, nonesterified fatty acids, or HDL cholesterol.

However, a 10% decrease in LDL cholesterol ($P < 0.05$) and a tendency to a larger decrease in total cholesterol ($P = 0.06$) were observed with consumption of the LGI diet as compared with the HGI diet.

Author Conclusion:

The most important finding of this study was the lack of difference between groups in energy intake, body weight, and fat mass changes after 10 weeks ad libitum consumption of the low-glycemic-index or high-glycemic-index diet by slightly overweight women. This study does not support the contention that low-fat low glycemic index diets are more beneficial than high-glycemic index diets with regard to appetite or body weight regulation as evaluated over 10 weeks. However, it confirms previous findings of a beneficial effect of low glycemic index diets on risk factors for ischemic heart disease.

Reviewer Comments:

Well designed study.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes

3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	???
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A

3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	No
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	No
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	No
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	Yes
6.6.	Were extra or unplanned treatments described?	Yes

6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	Yes
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes

10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes